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| 10/016,647 | 12/10/2001 | Carl Johan Friddle | LEX-0284-USA | 3815 |

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LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

| EXAMINER | |
|---|---|
| BUNNER, BRIDGET E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/016,647 | FRIDDLE ET AL. | |
| | Examiner | Art Unit | |
| | Bridget E. Bunner | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3 and 5-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/12/02; 12/13/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application, Amendments and/or Claims*

The amendment of 12 August 2004 has been entered in full. Claims 2 and 4 are cancelled. Claims 5-11 are added.

### *Election/Restrictions*

Applicant's election without traverse of Group I, claims 1-3, drawn to an isolated nucleic acid molecule in the reply filed on 12 August 2004 is acknowledged.

Claims 1, 3, and 5-11 are under consideration in the instant application.

### *Information Disclosure Statement*

1. The information disclosure statement filed 13 December 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, two database citations have been crossed off the PTO-1449 because there were no copies present in the instant application.

2. Furthermore, the information disclosure statement filed 13 December 2002 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, the Applicant has not submitted an English language translation or an English language abstract for document DE 19841413C. Therefore, the Examiner has crossed off this citation on the PTO-1449.

***Specification***

3. The disclosure is objected to because of the following informalities:

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "NUCLEIC ACID MOLECULE ENCODING A HUMAN ION CHANNEL PROTEIN".

Appropriate correction is required.

***Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3, and 5-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, claims 1, 3, and 5-11 are directed to an isolated nucleic acid molecule comprising at least 24 contiguous bases of SEQ ID NO: 1. The claims also recite an isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2. The claims recite that the nucleic acid molecule comprises the

nucleotide sequence of SEQ ID NO: 1. The claims also recite an isolate expression vector comprising the nucleic acid molecule and a host cell comprising the expression vector.

The specification discloses that the "present invention relates to the discovery, identification, and characterization of nucleotides that encode a novel human protein, and the corresponding amino acid sequence of this protein" (pg 1, lines 29-30 through pg 2, lines 1-2). The specification also discloses that the novel human protein described "shares structural similarity with mammalian ion channel proteins, particularly potassium channels, and more particularly voltage-gated potassium channel proteins" (pg 2, lines 2-5). However, the instant specification does not teach any significance or functional characteristics of the human polynucleotide (SEQ ID NO: 1) or polypeptide (SEQ ID NO: 2). The specification also does not disclose any methods or working examples that indicate the polynucleotide and polypeptide of the instant invention are involved in any activities. Since significant further research would be required of the skilled artisan to determine how the claimed nucleic acid molecule and polypeptide are involved in any activity, the asserted utilities are not substantial. Relevant literature reports that potassium channels constitute the most diverse class of ion channels with respect to kinetic properties, regulation, pharmacology, and structure (pg 1329, col 2; Tables 3-4; Lehmann-Horn et al. Physiol Rev 79 (4): 1317-1372, 1999). Additionally, over 13 potassium channel subfamilies have been identified in humans in both excitable and non-excitable cell types (Lehmann-Horn et al., pg 1329, col 2; pg 1330, col 1; Chavez et al. J Biol Chem 274(12): 7887-7892, 1999, pg 7887, ¶ 1). The channels are involved in the control of a variety of cellular functions, including neuronal firing, cellular proliferation, and neurotransmitter and hormone secretion (Chavez et al., pg 7887, ¶ 1). The specification asserts the following as patentable utilities for the claimed putative nucleic acid molecule (SEQ ID NO: 1):

1) to inhibit or enhance the expression of novel human proteins (NHPs) (pg 2, lines 12-18)

2) to generate mutant nucleotides or chimeric fusion proteins (pg 4, lines 10-19)

3) as hybridization probes (pg 5, lines 27-33; pg 6, lines 1-28)

4) to create a genomic library or expression library (pg 13, lines 17-33; pg 14, lines 1-17)

5) to construct a transgenic animal (pg 2, lines 18-32; pg 17, lines 14-33 through pg 19, lines 1-4)

6) in gene therapy (pg 16, lines 15-24)

7) in chromosome mapping (pg 3, lines 2-6)

8) in diagnostic or prognostic assays (pg 8, lines 6-16)

Each of these shall be addressed in turn.

*1) to inhibit or enhance the expression of novel human proteins (NHPs).* This asserted utility is not specific or substantial. Such can be performed for any polynucleotide. Further, the specification does not disclose specific cDNA, DNA, or RNA target sequences that would be utilized to inhibit or enhance protein expression. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*2) to generate mutant nucleotides or chimeric fusion proteins.* This asserted utility is not specific or substantial. Such assays can be performed with any polynucleotide. Further, the specification discloses nothing specific or substantial for the mutant polynucleotide or chimeric polynucleotide that is produced by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*3) as hybridization probes.* This asserted utility is not specific or substantial. Hybridization probes can be designed from any polynucleotide sequence. Further, the specification does not disclose specific cDNA, DNA, or RNA targets. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*4) to create a genomic library or an expression library.* This asserted utility is not specific or substantial. Such can be performed for any polynucleotide. Further, the specification does not disclose a specific nucleic acid sequence used to generate the library. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*5) to construct a transgenic animal.* This asserted utility is not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or translocated gene of the instant application (SEQ ID NO: 1). Significant further experimentation would be required of the skilled artisan to identify such a disease. The specification discloses nothing about whether the gene will be "knocked in" or "knocked out" or what specific tissues and cells are being targeted. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*6) in gene therapy.* This asserted utility is specific or substantial. Such can be performed for any polynucleotide. Further, the specification does not disclose any diseases or conditions associated with a mutated, deleted, or translocated gene of the instant application (SEQ ID NO: 1). Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*7) in chromosome mapping.* This asserted utility is not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification does not disclose a specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*8) in diagnostic or prognostic assays.* This asserted utility is not specific or substantial. Such assays can be performed with any polynucleotide. Further, the specification does not disclose the tissues or cell types the polynucleotide is normally and abnormally expressed in. The specification also discloses nothing about the normal levels of expression of the polynucleotide or a specific DNA target. Additionally, the specification does not disclose disorders or conditions associated with a mutated, deleted, or translocated gene (SEQ ID NO: 1). Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

6. Claims 1, 3, and 5-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

However, even if, arguendo, the claimed invention is eventually deemed to have a credible, specific and substantial asserted utility or a well established utility, claims 1, 6, and 9 would remain rejected under 35 U.S.C. § 112, first paragraph. The specification teaches that corresponding NHP homologs from other species are encompassed by the invention (pg 4, lines 3-5). The specification discloses that the present invention "contemplates any nucleotide

sequence encoding a contiguous NHP open reading frame (ORF) that hybridizes to a complement of a DNA sequence presented in the Sequence Listing" (pg 4, lines 24-29). The specification discloses that "any NHP proteins encoded by the NHP nucleotide sequences described above are within the scope of the invention, as are any novel polynucleotide sequences encoding all or any novel portion of an amino acid sequence presented in the Sequence Listing" (pg 19, lines 26-31). However, the specification does not teach any variants or fragments of the polynucleotide (SEQ ID NO: 1) of the instant application. The specification also does not teach functional or structural characteristics of the polynucleotide or polypeptide fragments recited in the claims.

The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). For example, Lehmann-Horn et al. teach that a single point mutation in voltage-gated Kv1.1, the human homolog of the *Shaker* potassium channel, causes episodic ataxia with myokymia (Lehmann-Horn et al. Physiol Rev 79 (4): 1317-1372, 1999; pg 1351; Figure 15; Table 12). However,

Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the polynucleotide and protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

7. Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated or cultured cell comprising an expression vector, does not reasonably provide enablement for a host cell comprising an expression vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Examiner has interpreted the claims as reading on isolated host cells, as well as host cells in the context of a multicellular, transgenic organism and host cells intended for gene therapy. The specification of the instant application teaches that NHP gene products (SEQ ID NO: 1) can be expressed in transgenic animals and any technique known in the art may be used to introduce a NHP transgene into animals to produce the founder lines of transgenic animals (pg 2, lines 18-32; pg 17, lines 14-33 through pg 19). However, there are no methods or working examples disclosed in the instant application whereby a multicellular animal with the incorporated NHP gene of SEQ ID NO: 1 is demonstrated to express the NHP peptide. There are also no methods or working examples in the specification indicating that a multicellular animal has NHP "knocked out". The unpredictability of the art is *very high* with regards to making transgenic animals. For example, Wang et al. (Nuc. Acids Res. 27: 4609-4618, 1999; pg 4617) surveyed gene expression in transgenic animals and found in each experimental animal with a single "knock-in" gene, multiple changes in genes and protein products, often many of which were unrelated to the original gene. Likewise, Kaufman et al (Blood 94: 3178-3184, 1999) found transgene expression levels in their transfected animals varied from "full" (9 %) to "intermediate" to "none" due to factors such as "vector poisoning" and spontaneous structural rearrangements (pg 3180, col 1, 2$^{nd}$ full paragraph; pg 3182-3183). Additionally, for example, the specification discloses that two possible techniques used to introduce a NHP transgene into

animals include pronuclear microinjection and gene targeting in embryonic stem cells. However, the literature teaches that the production of transgenic animals by microinjection of embryos suffers from a number of limitations, such as the extremely low frequency of integration events and the random integration of the transgene into the genome which may disrupt or interfere with critical endogenous gene expression (Wigley et al. Reprod Fert Dev 6: 585-588, 1994). The inclusion of sequences that allow for homologous recombination between the transgenic vector and the host cell's genome does not overcome these problems, as homologous recombination events are even rarer than random events. Therefore, in view of the extremely low frequency of both targeted and non-targeted homologous recombination events in microinjected embryos, it would have required undue experimentation for the skilled artisan to have made any and all transgenic non-human animals according to the instant invention. Furthermore, regarding gene targeting in embryonic stem cells, the specification does not provide guidance for identifying and isolating embryonic stem cells or for identifying other embryonal cells which are capable of contributing to the germline of any animal. At the time of filing, Campbell et al. teaches that, "in species other than the mouse the isolation of ES cells has proved more difficult. There are reports of ES-like cell lines in a number of species...However, as yet there are not reports of any cell lines which contribute to the germ line in any species other than mouse" (Campbell et al. Theriology 47(1): 63-72; see pg 65, 2nd paragraph). Thus, based on the art recognized unpredictability of isolating and using embryonic stem cells or other embryonal cells from animals other than mice to produce transgenic animals, and in view of the lack of guidance provided by the specification for identifying and isolating embryonal cells which can contribute to the germ line of any non-human mammal other than the mouse, such as dogs or cows, the

skilled artisan would not have had a reasonable expectation of success in generating any and all non-human transgenic animals using ES cell technology.

The specification also discloses that "nucleotide constructs encoding such NHP products can be used to genetically engineer host cells to express such products in vivo" and that these products can be used in gene therapy approaches for the modulation of NHP expression (pg 16, lines 15-24). However, the specification does not teach any methods or working examples that indicate a NHP nucleic acid is introduced and expressed in a cell for therapeutic purposes. The disclosure in the specification is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. For example, the specification does not teach what type of vector would introduce the NHP nucleic acid into the cell or in what quantity and duration. Relevant literature teaches that since 1990, about 3500 patients have been treated via gene therapy and although some evidence of gene transfer has been seen, it has generally been inadequate for a meaningful clinical response (Phillips, A., J Pharm Pharmacology 53: 1169-1174, 2001; abstract). Additionally, the major challenge to gene therapy is to deliver DNA to the target tissues and to transport it to the cell nucleus to enable the required protein to be expressed (Phillips, A.; pg 1170, ¶ 1). Phillips also states that the problem with gene therapy is two-fold: 1) a system must designed to deliver DNA to a specific target and to prevent degradation within the body, and 2) an expression system must be built into the DNA construct to allow the target cell to express the protein at therapeutic levels for the desired length of time (pg 1170, ¶ 1). Therefore, undue experimentation would be required of the skilled artisan to introduce and express a NHP nucleic acid into the cell of an organism. Additionally, gene therapy is unpredictable and complex wherein one skilled in the art may not necessarily be able to

introduce and express a NHP nucleic acid in the cell of an organism or be able to produce a NHP protein in that cell.

Due to the large quantity of experimentation necessary to generate a transgenic animal expressing the NHP protein and to introduce and express a NHP nucleic acid in a cell of an organism for therapy, the lack of direction/guidance presented in the specification regarding how to introduce a NHP nucleic acid in the cell of an organism to be able produce that NHP, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of making transgenic animals and the unpredictability of transferring genes into an organism's cells, and the breadth of the claims which fail to recite any cell type limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. (Please note that this issue could be overcome by amending the claims to recite, for example, "An isolated host cell...").

8. Claims 1, 6, and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites an isolated nucleic acid molecule comprising at least 24 contiguous bases of SEQ ID NO: 1. The claims also recite an expression vector comprising the nucleic acid molecule and a host cell comprising the expression vector.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus.

The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of 24 contiguous bases of SEQ ID NO: 1. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. It is noted that the specification only teaches a novel human protein (NHP) polynucleotide (SEQ ID NO: 1) and a polypeptide encoded by the nucleotides of SEQ ID NO: 1. However, the specification does not teach functional or structural characteristics of the polynucleotide in the context of a cell or organism. The description of one polynucleotide species (SEQ ID NO: 1) and one polypeptide species (SEQ ID NO: 2) is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides which incorporate all variants and fragments with at least 24 contiguous bases of SEQ ID NO: 1.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity

of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 1 and an isolated nucleic acid molecule that encodes the amino acid sequence of SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Priority***

Applicant's claim for priority under 35 U.S.C. 119(e) is acknowledged. The polynucleotide of SEQ ID NO: 1 and the polypeptide of SEQ ID NO: 2 of the instant application are fully disclosed in the prior application of 60/257,932 (20 December 2000).

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 6, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (US 20040014945A1).

Tang et al. teach an isolated nucleic acid molecule comprising at least 24 contiguous bases of SEQ ID NO: 1 of the instant application (See sequence alignment attached to this Office Action as Appendix A; see nucleotides 920-1648 of SEQ ID NO: 39 of Tang et al.; see also nucleotides 154-1242 of SEQ ID NO: 1 of the instant application). Tang et al. also disclose that the nucleic acid molecule of SEQ ID NO: 39 or derivatives thereof may be inserted into an appropriate expression vector which contains the necessary elements for transcriptional and translation control (pg 20, col 1, [0187]). Tang et al. teach that a variety of host systems may be utilized to contain and express sequences encoding the protein, called TRICH. Tang et al. teach such systems include bacteria, yeast, insect cells, plant cells, or animal cells (pg 20, col 2, [0189-0191] through pg 21).

It is noted that Tang et al. first disclose the polynucleotide of SEQ ID NO: 39 in provisional application 60/250,790 filed 01 December 2000, and therefore this date has been used for purposes of applying art.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
20 October 2004

Bridget E. Bunner